

### **REMARKS**

Applicant first thanks the Examiner for the telephone conversation on June 17, 2011 which clarifies the status of the present Office Action as non-final. Applicant also thanks the Examiner for withdrawing the rejection to claim 50 under 35 U.S.C. 102(b) as being anticipated by Lewis, Lon (Feeding and Care of the Horse second edition; 1995, Blackwell Publishing Professional, Ames, Iowa) in view of the amendment to claim 50 in the previous Response to Office Action on February 28, 2011.

By the foregoing Amendment, claims 25, 27-29, 34, 36, 43 and 50 are amended, and claim 26 is cancelled. No new matter is added as the amended limitations in the above claims have been disclosed previously, *inter alia*, in the original claims 26 and 52, and paragraphs [0015], [0016], [0019], [0020], [0022], [0023] and [0025]. Entry of the Amendment, and favorable consideration thereof, are earnestly requested. Of these claims, claims 25 and 50 are the only independent claims.

#### Claim Objection

The Examiner objected to the misnumbered claim 51. Applicant has renumbered it as claim 53 to overcome the claim objection.

#### Claim Rejections – 35 U.S.C. 102(b)

The Examiner rejected claims 25, 27-29, 32-34, 36, 38, 43 and 50 under 35 U.S.C. 102(b) as being anticipated by The American journal of obstetrics and diseases

of women and children 1912, volume 66, W. Wood & Co., pp 893-894 (referred to herein as "the Journal") as evidenced by Barth et al. (Nahrung 1997, 41(1): 2-12 Abstract only). Applicant respectfully submits that claims 25, 27-29, 32-34, 36, 38, 43 and 50 are not anticipated or obvious in view of these references.

The Journal discloses methods of treating gastritis in an infant with a sweet whey powder in water (pages 893-894). No fat is present in the sweet whey powder and water composition, as acknowledged by the Examiner.

Barth et al. discloses that whey inherently contains numerous vitamins and minerals (Abstract). Thus the Examiner stated the methods of treating gastritis in an infant disclosed in the Journal inherently using a composition comprising numerous vitamins and minerals.

Claims 25 and 50, as amended, require feeding a mammal with an energy deficiency or in a critical condition due to digestive tract disease with a composition having between *about 2% to about 2.5% fat* (referred to herein as "the fat limitation") comprising a protein component containing whey powder (referred to herein as "the whey powder limitation").

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Variet Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Missing

element may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985). Since neither the Journal nor Barth et al. discloses the fat limitation, the amended claims 25 and 50, and all dependent claims, 27-29, 32-34, 36, 38 and 43, are not be anticipated or obvious in view of these references.

Moreover, claims 27-29, 34, 36 and 43 have been amended to require additional vitamin, mineral, or other nutrient component in the composition *besides* those inherently contained in whey powder. Because neither the Journal nor Barth et al. discloses the inclusion of additional vitamins or minerals besides those inherently contained in whey powder, the amended claims 27-29, 34, 36 and 43 are not anticipated by the Journal as evidenced by Barth et al.

Claim Rejections – 35 U.S.C. 103(a)

The Examiner rejected claims 25-38, 40-48, 50, 52 and 53 under 35 U.S.C. 103(a) as being unpatentable over Lewis, Lon (Feeding and Care of the Horse second edition; 1996, Lipponcott Williams and Wilkins, Media, Pa) (referred to herein as "Lewis 1996") and Lewis, Lon (Equine Clinical Nutrition Feeding and Care; 1995, Williams & Wilkins, Media, Pa) (referred to herein as "Lewis 1995") and Parsons, HS., (Care and Management of the Older Horse; 2001, Trafalgar Square Publishing, North Pomfret, Vermont) and Weese et al. (Abstract; J. Am Vet. Med. Assoc 1999, 214(2), 229-32).

Applicant respectfully submits that claims 25-38, 40-48 and 50 are not obvious in view of these references.

Lewis 1996 teaches that common horse feed may contain proteins, carbohydrates, 2%-6% fat, minerals and vitamins. The proteins may come from various protein supplements (the table on page 64, and page 88, right column). Dehydrated skimmed milk is the most commonly used protein supplement fed to horses. Other milk products can also be added to horse feeds such as dried whole milk, dried whey, cheese rind, and dried buttermilk (page 88, right column). Lewis 1996 teaches that most horses, healthy or sick, do not need a special diet. However, "[f]or some specific disease conditions a specialized diet may be beneficial in minimizing the effects of and maximizing recovery from that disease. A specialized diet is one that contains more and/or less of one or more nutrients than those commonly fed to the normal healthy animal." (page 289, left column). But Lewis 1996 does not disclose compositions for any specialized diet. Instead, Lewis 1996 only offers *general* diet criteria for horses with liver diseases, that is, a diet that meets energy needs, protein needs, and be low in or not added fat (page 296, left column).

Nowhere in Lewis 1996 discloses a specialized diet comprising "a protein component comprising whey powder" or "between about 2% to about 2.5% fat." In fact, the word "whey" has not appeared anywhere in horse feed under the specific disease conditions such as diarrhea (a digestive tract condition), liver disease (hepatic dysfunction)

and kidney failure (renal dysfunction) in Lewis 1996. Simply because a horse feed program for *healthy* horses may contain protein supplements (of which, whey powder is only one choice) does not render the claims obvious because there is no teaching or evidence that one skilled in the art would recognize that whey could or should be included in a composition or feed program with between about 2% to about 2.5% fat by weight that is administered to a mammal with hepatic dysfunction, renal dysfunction, or digestive tract disease. For the same reason, simply because common horse feed for *healthy* horses may contain 2%-6% fat does not render the claims obvious because there is no teaching that a specific diet for a mammal with hepatic dysfunction, renal dysfunction, or digestive tract *diseases* could or should be a composition with whey and containing between about 2% to about 2.5% fat by weight. In fact, the present invention teaches methods of providing a special diet, which is different from a normal diet, for a mammal that becomes energy deficit due to hepatic dysfunction, renal dysfunction, or digestive tract disease.

Moreover, Lewis 1996 actually teaches away from feeding horses having the above mentioned diseases with whey powder because whey provides a high protein source. For example, Lewis 1996 teaches that the protein intake for horses with kidney diseases must be *limited* (page 15, right column) and avoid lugmens because of their high protein content (page 296, right column); for horses with liver diseases, a proper diet is in the form of alfalfa or a *lower-protein* grass forage.

Lewis 1996 also teaches away from feeding horses having a digestive tract condition with whey powder because whey powder is lactose enriched. Lewis 1996 states that if lactose is consumed in sufficient quantity, it causes diarrhea (a digestive tract condition). Thus Lewis 1996 suggests that whey powder is incompatible with a horse with a digestive tract condition.

Whey powder itself may contain up to 1% fat (Application, paragraph [0051]). To have about 2% to about 2.5% fat in the composition according to the present invention may need to include additional fat component, which is contrary to the teaching of Lewis 1996.

In short, Lewis 1996 does not teach a diet composition having the fat limitation and the whey limitation for treating with an energy deficiency or in critical care conditions due to hepatic dysfunction, renal dysfunction, or digestive tract disease.

Lewis 1995 and Parsons also fail to teach the methods using a diet composition having between about 2% to about 2.5% fat by weight and a protein component comprising whey powder for treating an energy deficit mammal due to hepatic dysfunction, renal dysfunction, or digestive tract disease. Rather, Parsons teaches a high fiber and low protein diet for horses having liver diseases. Such horses should "avoid high-protein feeds" and that the horse should be fed "late-cut hay (which is generally lower in protein)." (Parsons, page 236). "If in doubt, therefore, maintain your horse on a solely high

fiber diet..." (Parsons, page 237). Thus, a combination of Lewis 1996, Lewis 1995, and Parsons would only lead to treating energy deficient horses with a diet composition having high fiber, low protein, and low fat.

While Weese et al. teaches the administration of lactase to treat lactose intolerant foal, it does not address treating a horse with an energy deficiency due to hepatic dysfunction, renal dysfunction, or digestive tract diseases. Additionally, the subject of Weese et al. is a foal, less than one year old, but accordingly to Lewis 1996, the young horses less than 3 years of age have no lactose intolerance problem to be treated. Therefore, it would not be obvious for a person with ordinary skills in the art to combine Weese et al. with Lewis 1996.

Because Weese et al. does not teach the fat limitation or the whey limitation, Weese et al. and Lewis 1996, and other cited references, even if combined, would not arrive at claim 25 and 50.

For the above reasons, Applicant respectfully submits that the amended claims 25 and 50 are not obvious in view of the cited references. Accordingly, all dependent claims are patentable.

Respectfully submitted,

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/Wesley W. Whitmyer, Jr./

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